

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.; Hon. F. Kay Behm
ROBIN ROE 1 through 10, gender
neutral fictitious names; and ABC
CORPORATION 1 through 10
(fictitious names).

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS,
INC.'S OPPOSITION TO PLAINTIFF'S MOTION TO EXCLUDE
TESTIMONY OF MANSOOR M. AMIJI, PH.D.**

Pursuant to Local Rule 7.1(c) of the United States District Court for the Eastern District of Michigan, Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. (“BlueWillow”), by and through its undersigned counsel, Foley & Lardner LLP, hereby responds to Plaintiff/Counter-Defendant Trutek Corp.’s (“Trutek”) Motion to Exclude Testimony of Mansoor M. Amiji, Ph.D.

For the reasons stated in the accompanying Brief in Support, the Court should deny Trutek’s Motion.

Dated: May 26, 2023

Respectfully submitted,

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INC.'S BRIEF IN SUPPORT OF OPPOSITION TO PLAINTIFF'S
MOTION TO EXCLUDE TESTIMONY OF MANSOOR M. AMIJI, PH.D.**

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STATEMENT OF ISSUE PRESENTED

1. Whether the Court should exclude Dr. Amiji's expert testimony on issues related to invalidity of the '802 patent.

BlueWillow's answer: **No.**

Trutek's answer: **Yes.**

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I. INTRODUCTION

Plaintiff Trutek Corp.’s Motion to Exclude Testimony of Mansoor M. Amiji, Ph.D. (ECF 61) is full of conclusory, unsupported argument.¹ The premise of Trutek’s Motion is that Dr. Amiji’s opinions are “legal opinions” directed to issues of patent invalidity, and because he is not a lawyer and is unfamiliar with patent law, he is not permitted to provide opinions on patent invalidity. Not only does Trutek mischaracterize Dr. Amiji’s opinions, but it also baldly asserts that Dr. Amiji’s opinions are “routinely excluded” without citing any cases that reach this conclusion. That is not surprising, because Courts routinely allow qualified technical experts to provide opinion testimony on issues of patent invalidity based on their knowledge, skill, training and experience in the relevant art. Indeed, it is not technical expert testimony from an expert such as Dr. Amiji that is routinely excluded, but rather, expert testimony from patent lawyers such as Trutek’s expert Mr. Haidri that is routinely excluded. The remainder of Trutek’s arguments, including that Dr. Amiji is unqualified because he is a person of “extraordinary skill,” are also without merit.

¹ Trutek’s Motion does not conform to Local Rules 7.1(a), 7.1(d)(1) or 7.1(d)(3). Trutek’s Motion does not contain the required statement as to whether it sought concurrence in the relief sought prior to filing the motion. E.D. Mich. LR 7.1(a). There is no clearly identified brief in support of Trutek’s motion. E.D. Mich. LR 7.1(d)(1). Even assuming Trutek’s “brief” starts with the “Background Information” section, it is still well over the 25-page limit and there has been no order extending this page limit. E.D. Mich. LR 7.1(d)(3). Regardless of all these deficiencies, BlueWillow has responded to all arguments contained in Trutek’s motion.

Dr. Amiji is a qualified technical expert, whose expert reports and proposed testimony on behalf of Defendant BlueWillow Biologics, Inc. on issues related to invalidity of U.S. Patent No. 8,163,802 (“the ’802 patent”) is well supported by the reliable application of methods to relevant facts, and his scientific and technical knowledge of the relevant art will assist the trier of fact on issues of patent invalidity. Dr. Amiji’s proposed testimony and opinions are admissible under Fed. R. Evid. 701, 702 and 704, and Trutek’s Motion (ECF 61) should be denied in its entirety.

II. FACTUAL BACKGROUND

As noted in Plaintiff’s Motion, Dr. Amiji is a qualified expert in pharmaceutical sciences. ECF 61 at 2-3. He has testified as a technical expert in over 18 cases in the past four years in front of both federal courts and the Patent Trials and Appeal Board. ECF 52-2 at 7-8. Indeed, Plaintiff does not question Dr. Amiji’s qualifications. ECF 61 at 2-3. Defendant BlueWillow submitted three expert reports from Dr. Amiji: (1) Opening Expert Report (*see* **Ex. 1**), on technical patent invalidity issues related to (a) anticipation (§ 102) and obviousness (§ 103), (b) subject matter eligibility (§ 101), and (c) utility, written description, and enablement (§ 112); (2) Responsive Expert Report to Edward Lemmo’s, Alexei Ermanov’s, and Shane Burns’ Reports on issues related to infringement; and (3) Reply Report to Edward Lemmo’s and Amirali Haidri’s Reports on issues related to invalidity. Trutek’s Motion is focused entirely on the opinions provided by Dr.

Amiji in his Opening Report, and does not address his invalidity opinions provided in his Reply Report (or his opinions on non-infringement). ECF 61.

Plaintiff's expert, Amirali Haidri, submitted one expert report, responding to Dr. Amiji's opening report (*see* **Ex. 2**) on invalidity issues. Mr. Haidri's report and proposed expert testimony are the subject of Defendant's Motion to Exclude as containing (1) impermissible legal opinion and argument from a patent attorney and (2) impermissible technical opinions from an expert who lacks the appropriate technical qualifications to testify as a person of ordinary skill in the art. ECF 56.

III. LEGAL STANDARD

A determination whether to admit expert testimony under Federal Rule of Evidence 702 is based on the *Daubert* reliability analysis. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). The testimony must (1) be based on sufficient facts or data, (2) be based on reliable methods, (3) involve reliable application of the methods to the facts of the case, (4) be related to the issues in the case. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 591-94.

“An opinion is not objectionable just because it embraces an ultimate issue.” Fed. R. Evid. 704. Courts addressing admissibility of expert testimony on issues of patent invalidity routinely permit properly qualified technical experts to provide opinion testimony on ultimate issues of patent invalidity as long as such testimony is adequately supported by facts. *E.g., Icon Health & Fitness, Inc. v. Strava, Inc.*,

849 F.3d 1034, 1041 (Fed. Cir. 2017); *Formax, Inc. v. Alkar-Rapidpak-MP Equip., Inc.*, No. 11-C-298, 2014 WL 3057116, at *2 (E.D. Wis. July 7, 2014); *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, No. 6:09-cv-1698-Orl-19KRS, 2010 WL 3123129, at *5 (M.D. Fl. Aug. 9, 2010).

A technical expert may not testify as to invalidity unless they are qualified in the pertinent art. *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363-64 (Fed. Cir. 2008). However, once qualified, admission of expert testimony is within the discretion of the trial court. *See Acoustical Design, Inc. v. Control Elecs. Co.*, 932 F.2d 939, 942 (Fed. Cir. 1991).

IV. ARGUMENT

Plaintiff's motion demonstrates a fundamental misunderstanding of the role of technical experts in patent infringement cases and mischaracterizes the testimony Dr. Amiji will offer at trial on issues directed to patent invalidity. Dr. Amiji is not offered as a "patent law expert" and is not providing "legal opinions" on patent invalidity (Issues 1-3). Dr. Amiji is a qualified technical expert, who has prepared two expert reports detailing his technical expert opinions on issues of patent invalidity. Dr. Amiji's opinions on the ultimate issue of patent invalidity are adequately supported by application and consideration of relevant factual considerations and are admissible under Fed. R. Evid. 702, 703 and 704 (Issue 4).

Plaintiff's Issue 5 ("Dr. Amiji's legal opinions are routinely excluded in whole or in part to show patent invalidity in patent infringement trials") is also incorrect. As addressed herein, technical expert testimony on patent invalidity is routinely allowed in patent infringement cases. "Invalidity of patents . . . has been recognized as an appropriate subject for expert testimony." *StoneEagle Servs. v. Pay-Plus Solutions, Inc.*, Case No. 8:13-cv-2240-T-33MAP, 2015 U.S. Dist. LEXIS 79955, at *6-10 (M.D. Fl. June 19, 2015) (rejecting argument that technical expert was not qualified to provide testimony on patent invalidity because he "lacks any background or experience regarding patents, patent invalidity, or patent non-infringement," noting that because he "has not been offered in that capacity [as a patent law expert], his lack of expertise in that area is not dispositive of his qualifications"); *see also* Fed. R. Evid. 704.

The remainder of Plaintiff's arguments are also without merit. Disagreement with an expert's opinions or conclusions is not sufficient to exclude their testimony. *See, e.g.*, ECF 61 at 31 ("When asked whether a formulation that actually inhibits infection due to inhalation of harmful particles would be useful, he said it would not."). Disagreement with the legal standards considered by an expert also does not warrant excluding the expert's *technical testimony*. *See, e.g., id.* ("[H]is opinions show that he does not understand the law and that he misinterpreted the meaning of

the statutes and the standards of review stemming therefrom.”). Correct application of the law is an issue for the Court, not for experts.

Consistent with what technical experts have done in other cases, and as permitted by the Federal Rules of Evidence, Dr. Amiji has described the facts and data relevant to his inquiry, and offered his opinion on patent invalidity based on application of those facts and his understanding of patent law as provided by counsel.

A. Dr. Amiji’s Testimony Is Appropriate

1. Dr. Amiji Is Qualified to Provide Testimony From the Perspective of a POSA

Plaintiff’s argument that Dr. Amiji’s testimony should be disallowed because he is a person of *extraordinary* skill in the art is meritless. ECF 61 at 11-12. A person of ordinary skill in the art (“POSA”) is a theoretical construct who is presumed to be aware of all pertinent prior art. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). The POSA is a hypothetical person and not descriptive of a particular individual. *See Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997). In order to offer testimony from the perspective of a POSA, an expert must have *at least* ordinary skill in the art. *See Kyocera Senco Indus. Tools, Inc. v. International Trade Comm’n*, 22 F.4th 1369, 1377 (Fed. Cir. 2022). As such, the standard cannot be used to disqualify an expert of extraordinary skill in the art. *See*

Endress, 122 F.3d at 1042; *Kyocera*, 22 F.4th at 1377 (“[A]s *Endress* recognized, it would be improper to require an expert witness to possess ordinary skill in the art and *nothing more*. If that were the case, ‘a person of exceptional skill in the art would be disqualified from testifying as an expert because [he is] not ordinary enough.’”).

As acknowledged by Plaintiff, Dr. Amiji possesses *at least* the qualifications of a POSA, as defined by the Court in this matter.² ECF 61 at 2-3. Plaintiff is clearly not arguing that Dr. Amiji is less qualified than a POSA. As such, there is no reason to disallow Dr. Amiji’s testimony on the basis of his technical qualifications.

2. Dr. Amiji Does Not Need to Be a Patent Law Expert

Technical experts are not required to be patent law experts to act as an expert witness. *See Endress*, 122 F.3d at 1042 (“It is of course nonsense to contend that only lawyers or patent lawyers can be expert witnesses in a patent suit.”). Rather, it is an abuse of discretion for a court to exclude an otherwise qualified expert because they are not a lawyer. *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695

² Defendant does not dispute the POSA definition adopted by the Court (ECF 53), but notes that definition recited in Plaintiff’s Motion at page 11 is incomplete. *See* ECF 40 at PageID.737-738 (Lemmo Decl.). Dr. Amiji also addressed the adopted definition in his reply report and claim construction declaration, noting how the lower standard impacts his Section 112 analysis and concluding that despite the lower standard, it did not impact any of his opinions provided in his opening report. ECF 38-3 at ¶¶ 21-23, 39-41; ECF 59-2 at PageID.1855, 1862-65 (¶¶ 20-23, 26).

F.3d 1285, 1296 (Fed. Cir. 2012) (“[E]xclusion of a technical expert for the reason that he is not a lawyer is contrary to Federal Rule of Evidence 702 and the benefits of technological assistance in resolution of technological issues.”).

Because technical experts are not required to be lawyers, they do not need to supply the legal standards relevant to their analysis. And, counsel are not precluded “from providing assistance to experts in preparing [the] expert reports, and indeed, . . . this assistance may be needed.” *WNS Holdings, LLC v. United Parcel Service, Inc.*, No. 08-cv-275, 2009 WL 2136961, at *4 (W.D. Wis. July 14, 2009) (citing Fed. R. Civ. P. 26(a)(2)(B) advisory committee note (1993)) (finding that even though counsel provided expert the legal standards, it did not follow that the expert’s opinions were merely parroting attorney argument.), *aff’d*, 368 F. App’x 144 (Fed. Cir. 2010). A technical expert’s lack of expertise in patent law does not undermine their expertise in their technical field. *See WNS Holdings*, 2009 WL 2136961, at *4.

Dr. Amiji is not a lawyer or an expert in patent law. Rather, as Plaintiff agrees, he is a highly qualified expert in pharmaceutical sciences and drug formulation development and characterization. ECF 61 at 2. Thus, Dr. Amiji is well qualified to speak on technical issues related to the ’802 patent, including issues of patent invalidity. Dr. Amiji’s opinions on patent invalidity are admissible because his “scientific, technical, or otherwise specialized knowledge will help the trier of fact

to understand the evidence or to determine a fact in issue,” and his opinions are “not objectionable just because it embraces an ultimate issue.” Fed. R. Evid. 702, 704.

It would be an abuse of discretion to exclude Dr. Amiji’s testimony on the basis that he lacks a qualification that is unnecessary. Any challenge to his lack of expertise as a patent lawyer does not cast any doubt on his ability to testify competently about the technical matters at issue. Likewise, Dr. Amiji was permitted, when drafting his report, to rely on legal standards provided to him by counsel. ECF 61 at 5 (citing Depo. Amiji 19:24; 20:3-6; 51:12-15); *see also StoneEagle*, 2015 U.S. Dist. LEXIS 79955, at *15-17. Instead of identifying legal standards himself, a process he is admittedly not qualified to perform, he relied on people who are qualified. *See Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303 (Fed. Cir. 2015).

3. The Legal Standards Used by Dr. Amiji Go to the Weight of his Testimony, Not the Admissibility³

Technical experts are not the source of legal standards, correct or otherwise. *See Plexxikon Inc. v. Novartis Pharms. Corp.*, No. 17-cv-04405-HSG, 2020 WL

³ Despite Plaintiff’s assertion, there is no confusion whether the AIA or pre-AIA version of the patent statute applies here. Patents having effective filing dates “on or after” September 16, 2012 are governed by the AIA. *See Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 n.3 (Fed. Cir. 2018) (citing AIA § 4(e), 125 Stat. at 297). Thus, all patents with effective filing dates before September 12, 2012, are subject to pre-AIA law. Plaintiff agrees the ’802 Patent is based upon a patent application filed in 2009. ECF 61 at 19. Thus, pre-AIA law applies.

2301213, at *2 (N.D. Cal. May 8, 2020) (agreeing with Plexxikon that “[i]ncorrect statements of law are no more admissible through experts than are falsifiable scientific theories”) (internal citations omitted). This is exclusively the province of the Court. As such, a technical expert’s misapprehension of patent law is not a reason to disallow their testimony. *See Formax*, 2014 WL 3057116, at *3 (E.D. Wis. July 7, 2014) (“The fact that an engineer does not know the burden of proof or the difference between anticipation and obviousness—something ninety-five percent of attorneys would not be able to explain—is not a reason to disqualify him.”); *Niazi Licensing Corp. v. St. Jude Medical. S.C., Inc.*, No. 17-cv-5096 (WMW/BRT), 2020 WL 5512507, at *5 (D. Minn. Sept. 14, 2020) (finding it inappropriate to exclude a technical expert who was unable to recite the difference between direct and indirect infringement).

While Plaintiff includes pages of argument that Dr. Amiji’s purported legal analysis is allegedly incorrect, it cites no case holding that his testimony must be excluded on this basis. *See* ECF 61 at 12-29. Indeed, a *Daubert* motion is not the proper procedure for addressing disputes over legal standards. BlueWillow disagrees with Plaintiff’s recitation of what it believes to be the applicable legal standards, but

does not address all of those issues here⁴ because those disagreements are addressed through jury instructions. *See Formax*, 2014 WL 3057116, at *3 (“What’s important is his expertise and whether he can demonstrate to the jury, which will be instructed in the substantive law as well as the burden of proof.”).

Even assuming, *arguendo*, that Dr. Amiji applied any incorrect legal standard, it does not warrant excluding his testimony. It is the opposing party’s role to point out any alleged errors during cross-examination so a jury may weigh the testimony. *See Marine Travelift Inc. v. ASCOM SpA*, No. 14-C-443, 2015 WL 9008254, at *1 (E.D. Wis. Dec. 15, 2015) (“If there are holes in [the expert’s] analysis, then MTI may point them out and they will factor in to the weight a court or jury ultimately

⁴ Some of Trutek’s assertions are blatantly incorrect and addressed here. *First*, a single prior art reference can render a patent obvious if it would have been obvious to modify that reference to arrive at the claimed invention (ECF 61 at 29, 31). *Game & Tech. Co. v. Activision Blizzard Inc.*, 926 F.3d 1370, 1381 (Fed. Cir. 2019); *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016). *Second*, the requirement that a claimed invention demonstrate a credible utility is derived from 35 U.S.C. §§ 101 and 112 (ECF 61 at 17). *In re ’318 Patent Infringement Litig.*, 583 F.3d 1317, 1323-24, 1328 (Fed. Cir. 2009). *Third*, Trutek does not acknowledge the correct standard for written description, which requires not just a mere description of the claimed invention, but rather, a description that “reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The ’802 patent does not claim a formulation, but rather, a formulation that performs specific functions. Thus, Dr. Amiji properly explained why the lack of test results in the specification is relevant to a POSA. ECF 61 at 20.

gives it.”). Plaintiff questioned Dr. Amiji on his understanding of patent law during his deposition and can do so at trial (as appropriate).

4. Dr. Amiji Did Not Provide Legal Opinions, and Experts Are Allowed to Offer Opinions on Ultimate Issues of Law

An expert is permitted to state the law he applied when reaching his conclusions; such a statement is relevant to determine if the testimony is credible and puts the testimony in context. *See Voter Verified, Inc. v. Premier Election Sols., Inc.*, No. 6:09-cv-1968-Orl-19KRS, 2010 WL 3123129, at *5 (M.D. Fla. Aug. 9, 2010) (rejecting motion to strike portion of expert report which cited legal definitions even though it was not scientific, technical, or other specialized knowledge as required by Fed. R. Evid. 702), *aff’d*, 698 F.3d 1374, 1384 and n.6 (Fed. Cir. 2012); *Medicines Co. v. Mylan*, No. 11-cv-1285, 2014 WL 1257943, at *2-3 (N.D. Ill. Mar. 27, 2014).

Additionally, experts are permitted to offer their opinion on ultimate issues of law. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985); *see also* Fed. R. Evid. 704(a) (“An opinion is not objectionable just because it embraces an ultimate issue.”). These opinions are of greater probative value if provided with factual support. *Ashland Oil*, 776 F.2d at 294. Specifically for issues of patent invalidity, “[a] technical expert’s role under these circumstances is to explain why earlier technology anticipates or renders obvious the claims of a

patent; in doing so, the expert is not rendering a legal opinion but merely a factual-expert opinion based on his own expertise and experience.” *Formax*, 2014 WL 3057116, at *2. Nor is there any prohibition against a technical expert stating that something “would have been obvious;” such statements must be viewed in context along with the entirety of the expert’s testimony. *See Icon Health*, 849 F.3d at 1041; *see also Voter Verified*, 2010 WL 3123129, at *5 (permitting expert to provide opinions on ultimate issue of patent invalidity due to obviousness and anticipation). Likewise, Courts routinely rely on technical expert testimony for issues under 35 U.S.C. § 112 and a POSA’s understanding. *See, e.g., In re ’318 Patent Infringement Litigation*, 583 F.3d 1317, 1326-27 (Fed. Cir. 2009); *Ziarno v. American Nat’l Red Cross*, 55 F. App’x 553, 555-556 (Fed. Cir. 2003); *Bone Care Intern., LLC v. Pentech Pharms., Inc.*, 862 F. Supp. 2d 790, 809-811 (N.D. Ill. 2012).

Plaintiff drastically mischaracterizes Dr. Amiji’s opening report by asserting that “[a]ll of the opinions that Dr. Amiji rendered in his opening expert report are legal opinions.” ECF 61 at 1; *see also* ECF 61 at 9. To support this assertion, Plaintiff identifies eight specific statements from Dr. Amiji’s opening report. *See* ECF 61 at 3-4. Six of these statements are merely section titles, a convenient road map to aid anyone reading the report. ECF 61 at 4, ¶¶ 2, 4-8; Ex. 1 at 44, 58, 74, 95, 101, 108. Another statement is a single sentence from the credible utility section of

Dr. Amiji's opening report. ECF 61 at 4, ¶ 3; Ex. 1 at ¶ 212. The final alleged "legal opinion" is Dr. Amiji's definition of a POSA for the '802 patent. ECF 61 at 4, ¶ 1.

In contrast, Dr. Amiji's opening report is 110 pages in length. Ex. 1. Each of these eight opinions on patent invalidity are supported throughout the remainder of his report with relevant facts, and the application of reliable methods to those facts. For example, Dr. Amiji's opinions that the asserted claims are invalid are supported by at least 10 pages of technical analysis providing an overview of the asserted patent and the related technology area. Ex. 1 at ¶¶ 56-64, 69-80 (pages 23-26, 28-33). Likewise, Dr. Amiji's opinions directed to invalidity of the asserted claims in view of the prior art are supported by over 60 pages of analysis providing a technical overview of the prior art references and detailed analysis of why the disclosures and teachings of the prior art render the asserted claims anticipated and/or obvious. Ex. 1 at ¶¶ 82-107 (pages 33-44); 108-200 (pages 44-94). The remaining 16 pages of Dr. Amiji's report also provide detailed technical analysis supporting the remainder of his opinions related to subject matter eligibility, credible utility, written description and enablement. Ex. 1 at ¶¶ 201-238 (pages 95-110).

For the reasons explained above, it would be error to exclude Dr. Amiji's testimony that the asserted claims are invalid merely because they "embrace[] an ultimate issue" to be decided in the case. Technical experts are permitted to offer

opinions on ultimate issues of law, particularly where, as here, those opinions are supported by extensive factual support and technical analysis.

5. Dr. Amiji's Opinions Are Reliable Under the *Daubert* Standard

While Plaintiff also argues that Dr. Amiji's opinions do not satisfy the *Daubert* standard, it provides no actual analysis of the facts and scientific methods used by Dr. Amiji. *See* ECF 61 at 2, ¶ 4. Plaintiff instead argues that because Dr. Amiji's understanding of patent law is (allegedly) incorrect, his opinion is based on unreliable methods. *See* ECF 61 at 32. This assertion is premised on a complete misunderstanding of *Daubert* and Fed. R. Evid. 702. Plaintiff cites no cases to support its novel reading of this case and Rule, and its argument should be disregarded for the reasons explained previously.

B. Dr. Amiji's Testimony Will Assist the Trier of Fact

The appropriateness of Dr. Amiji's expert testimony is all the more evident when contrasted with Plaintiff's invalidity expert, Mr. Haidri. While Dr. Amiji's opening report and related opinions of patent invalidity are supported by a robust analysis and explanation of the technology at issue in the case, the prior art, the disclosure of the '802 patent, and the understanding of such matters by the POSA, Mr. Haidri's report is almost entirely comprised of legal argument and case citations. *See* ECF 56. Indeed, Plaintiff and Mr. Haidri recognize that while the question of

patent invalidity is a question of law, it is one that is “to be determined from the facts.” *See* ECF 61 at 32. Each of Dr. Amiji’s opinions related to patent invalidity are adequately supported by factual and technical analysis, and “will help the trier of fact to understand the evidence or to determine a fact in issue” for the reasons explained below. *See* Fed R. Evid. 702.

a. Dr. Amiji’s Opinions Regarding Section 101 Patent Ineligibility

Patent eligibility is primarily a question of law, but there are underlying questions of fact for which expert testimony is helpful. *See Infernal Tech., LLC v. Sony Interactive Entertainment LLC*, No. 2:19-cv-00248-JRG, 2021 WL 405813, at *3 (E.D. Tex. Feb. 3, 2021) (permitting technical expert to testify as to “whether a person having ordinary skill in the art would understand the claim limitations, alone or in combination, to be routine, conventional, or well-understood.”). That is exactly the opinion offered by Dr. Amiji. For example,

205. . . . “[I]t is [] my opinion that each of the additional elements of the Challenged Claims recite nothing more than well-understood, routine and conventional activity or are directed to the very same law of nature or natural phenomena.

206. For example, a POSA would understand the desire to adjust “the adhesion of the thin film to permit said thin film to stick to the skin or tissue,” and the ’802 Patent specification and claims do not provide any further guidance as to how to do this or any unique method for doing so. Likewise, the claim element of “inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless” is also directed to well-understood,

routine, and conventional activity. As explained above QACs were known to have antimicrobial properties since the 1930s, and BAC is likewise a well-known and commonly used disinfectant.

207. [E]ach of the additional claim limitations are provided at only a general level, as opposed to describing a specific application of the natural law/phenomena. For example, there is no mention in the '802 patent claims as to: (1) the specific charge density or other quantitative parameters that will be needed to create the electrostatic field; (2) what magnitude of electrostatic field is necessary to attract oppositely charged contaminants; (3) how far the electrostatic field needs to be from the application surface; (4) how much of the product must be applied to be effective; or (5) how long the composition must stay on the skin to be effective. In other words, the '802 patent claims simply rely on the general presence of the electrostatic field/natural phenomena to achieve the claimed result and function.

Ex. 1 at ¶¶ 205-206, 207.

Plaintiff offers no argument for why Dr. Amiji is unqualified or should otherwise not be permitted to testify as to questions of fact. Instead, Plaintiff argues that Dr. Amiji is not qualified to testify as to this issue because “he does not know the meaning of the statute.” ECF 61 at 16. Dr. Amiji’s opinions are directed to factual issues of the same type considered by other Courts when assessing whether the claimed invention is patent eligible, *i.e.*, whether the claim limitations are routine, conventional, or well-understood. Dr. Amiji’s opinion that the asserted claims are not patent eligible is properly based on an adequately supported technical analysis of the underlying facts. As such, his opinions would be helpful to “assist the trier of fact” and are admissible under the relevant standards.

b. Dr. Amiji's Opinions Regarding Lack of Credible Utility

Under Sections 101 and 112, a patent must disclose a credible utility for the claimed invention. *In re '318 Patent*, 583 F.3d at 1325-27. The question of whether the '802 patent satisfies the utility requirement is not whether it discloses any utility, as Plaintiff suggests, but rather, **whether a POSA would view the disclosed utility as credible**. *Id.* at 1327 (discussing whether expert testimony demonstrated “that a person of ordinary skill in the art would have recognized that the specification conveyed the required assertion of a credible utility” and finding no credible utility where the specification did not provide any test results or other information demonstrating to a POSA that the claimed invention would work for its claimed purpose).

As such, testimony from a qualified technical expert directed to the factual question of whether a POSA would understand the '802 patent to disclose a credible utility is the proper subject for expert testimony. Dr. Amiji's opinions on credible utility fall squarely within this framework. More specifically, Dr. Amiji explains:

213. As an object of the claimed invention, the '802 Patent states that “to accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied.” '802 patent at 4:39-43.

214. A person skilled in the art reading the '802 patent specification, however, would understand that while the '802 patent

does provide a laundry list of possible formulations, it does not include any data or test results for any of the formulations described, demonstrating to a person skilled in the art that there is a substantial likelihood that the claimed invention will work by “electrostatically attracting” particulate matter to a thin film applied to the nasal passages and holding the particulate matter in place through adhesion to the thin film in order to electrostatically inhibit such harmful particulate matter from infecting an individual. Nor does the ’802 patent even provide any discussion or suggestion of what types of tests or procedures could be employed by a person skilled in the art to determine whether such formulations would work as described and claimed. Finally, the ’802 patent also does not include any explanation or suggestion that the claimed invention is likely to work based on any similarities or analogies to other compositions or formulations that are known to work in a similar manner.

216. As such, in my opinion, apart from its reliance on the previous and well-known properties of cationic agents such as QACs and BAC, the ’802 Patent provides no other information to a person skilled in the art to support the assertion that the claimed invention also works by “electrostatically inhibiting” harmful particulate matter from infecting an individual. In other words, a person skilled in the art reading the ’802 Patent specification would understand that it does not provide anything other than a hypothesis that the claimed invention operates to “electrostatically inhibit” harmful particulate matter from infecting an individual.

Ex. 1 at ¶¶ 213-14, 216.

Plaintiff does not argue that Dr. Amiji’s opinion regarding lack of credible utility is unsupported by any factual or technical analysis. Rather, Plaintiff argues that “Dr. Amiji presented opinions of a legal nature regarding 35 U.S.C. § 101” and “misinterpreted the requirements of the statute.” ECF 61 at 18. Dr. Amiji’s opinion that the asserted claims lack credible utility is properly based on an adequately

supported technical analysis of the underlying facts from the perspective of a POSA. *In re '318 Patent*, 583 F.3d at 1325-27. As such, his opinions would be helpful to “assist the trier of fact” and are admissible under the relevant standards.

c. Dr. Amiji’s Opinions Regarding Lack of Enablement and Written Description

Enablement is a question of law based on underlying findings of fact. *In re Vaeck*, 947 F.2d 488, 495-96 (Fed. Cir. 1991). To “be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365-66 (Fed. Cir. 1997). The so-called “Wands factors” describe the factual inquiries underlying the enablement question: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Written description is a “question of fact” assessing “whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351, 1355-56 (Fed. Cir. 2010).

Thus, issues of enablement and written description are both assessed from the perspective of a person skilled in the art and are based on factual findings. Likewise, the ultimate issue of invalidity based on lack of enablement and written description are both proper subjects for expert testimony. *Genentech*, 108 F.3d at 1365-66 (relying on technical expert testimony and opinions directed to issue of enablement); *Ariad*, 598 F.3d at 1336, 1351, 1356 (relying on technical expert testimony and opinions directed to this issue of written description).

Dr. Amiji's opinion directed to lack of enablement is supported by over 7 pages of technical and factual analysis from the perspective of a POSA. Ex. 1 at ¶¶ 218-35 (pages 101-08). More specifically, Dr. Amiji analyzes the: (1) nature of the invention and state of the prior art (*id.* at ¶¶ 219-20); (2) breadth of the claims (*id.* at ¶¶ 221-23); (3) amount of direction or guidance in the specification and absence of working examples (*id.* at ¶¶ 224-28); (4) level of skill in the art and unpredictability in the art (*id.* at ¶¶ 229-30); and (5) the quantity of experimentation required (*id.* at ¶¶ 231-35). For example,

224. While the '802 Patent contains a large list of possible formulations and components that are purportedly within the scope of the claimed invention, the patent does not teach or disclose which combinations or percentages of the different components are necessary to provide the claimed functionality of "electrostatically inhibiting" harmful particulate matter from infecting an individual.

226. [T]he '802 Patent does not provide any examples that include the results of any testing of any of the disclosed formulations,

let alone any guidance as to what types of tests should be conducted in order to determine whether a particular formulation would “operate in the manner” disclosed, e.g., by electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Nor does the ’802 Patent provide any examples or any guidance as to how the percentages of components can be varied while still achieving “the same results.”

227. Indeed, the ’802 Patent even acknowledges that varying the percentages of the ingredients can affect the potency of the formulation and the consistency of the formulation. A person skill in the art would understand that both of these attributes could impact the ability of the formulation to “render said particulate material harmless” and the claimed adhesive and electrostatic properties of the formulation. The ’802 Patent, however, does not provide any explanation or guidance as to how or to what degree “[v]arying the percentages for the active ingredients affects the potency of the formulation.” Nor does the ’802 Patent provide any explanation or guidance to how or to what degree “[v]arying the percentages for the inactive ingredients affects the consistency of the formulation.”

ECF 56-2 at ¶ 224-27.

Dr. Amiji’s opinion directed to lack of written description is also supported by technical and factual analysis from the perspective of a POSA. For example,

237. While the ’802 patent specification describes numerous formulations and different ranges of components that are purportedly within the scope of the claimed invention, the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to “electrostatically attract” negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual. Nor does the ’802 patent specification provide any indication to a person skilled in the art that the inventor even tested any of the formulations disclosed in the patent to assess whether they actually operate to electrostatically inhibit harmful particulate matter from infecting an individual through

nasal inhalation. In other words, a person skilled in the art reading the '802 patent would understand that the inventor merely had a wish or hope that the claimed invention would operate in the manner described.

238. More specifically, the '802 Patent provides ten separate tables, each with many listed components and percent ranges, yet provides no data explaining which formulations will operate to electrostatically attract oppositely charged particulate matter. Nor is there any explanation or disclosure within the '802 Patent that would demonstrate to a person skilled in the art that the mere fact of electrostatically inhibiting such particulate matter will be sufficient to render such particulate matter harmless. Particularly in view of the countless formulations and variable components encompassed by the claims, the specification of the '802 Patent would not indicate to a POSA that the inventors possessed the claimed subject matter.

ECF 56-2 at ¶ 237-38.

Plaintiff does not argue that Dr. Amiji's opinions regarding lack of enablement and lack of written description are unsupported by any factual or technical analysis. Again, Trutek merely argues that Dr. Amiji "does not fully understand" Trutek's view of the law. ECF 61 at 25. Dr. Amiji's opinions directed to enablement and written description are properly based on a well-supported technical analysis of the underlying facts. As such, his opinions would be helpful to "assist the trier of fact" and are admissible under the relevant standards.

d. Dr. Amiji's Opinions Regarding Anticipation and Obviousness in View of the Prior Art

Obviousness is a question of law based on underlying findings of fact. *In re Vaeck*, 947 F.2d at 496. "It is technological experience in the field of the invention

that guides the determination of obviousness.” *Outside the Box*, 695 F.3d at 1297. The relevant factual inquiries include the scope and content of the prior art, differences between the prior art and the claimed invention, and the level of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Anticipation, and the question of what a prior art reference discloses, are both questions of fact. *In re NTP*, 654 F.3d 1279, 1297 (Fed. Cir. 2011).

Dr. Amiji addressed each of these factual inquiries at length when reaching his opinions regarding obviousness and anticipation. Ex. 1 at ¶¶ 82-107 (pages 33-44); 108-200 (pages 44-94). Dr. Amiji has ample technical and scientific experience in the field of the invention. Dr. Amiji correctly applied that experience when offering his opinions on what a POSA would have understood from the disclosure of the prior art. Despite Plaintiff’s assertion to the contrary, the fact that Dr. Amiji may be a person of “extraordinary skill in the art” does not render his testimony inadmissible. *Kyocera*, 22 F.4th at 1377.

V. CONCLUSION

For the reasons stated herein, Plaintiff’s Motion to Exclude Testimony of Mansoor M. Amiji, Ph.D. should be denied in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on May 26, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

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